

REMARKS

Claim 26 is withdrawn from consideration as allegedly directed to an invention that is independent or distinct from the invention originally claimed. Claims 3, 6, 7, and 23-25 are currently pending.

Claims 3, 23 and 24 are amended to clarify that the claimed method is a method of selecting a maturation stage of *Echinacea* plants. No new matter is added by this amendment and support for the amendment may be found throughout the specification, including at the abstract, paragraphs 4, 5, 16, and 32, and previously pending claims 3 and 24. Claims 3 and 24 have also been amended by deleting reference to a step of preparing a standardized *Echinacea* extract. No new matter is added by this amendment.

Claims 3 and 24 are further amended to clarify that the marker compound is chicoric acid. No new matter is added by this amendment and support for the amendment may be found throughout the specification, including at the abstract, paragraphs 5, 17, 22, 24, 25, 32, and 33, Table 1, and original claims 10, 12, 15, 18 and 21. The standardized concentration of chicoric acid in claims 3 and 24 is also amended to clarify that the concentration ranges from about 3.26 % to about 3.62 % chicoric acid. No new matter is added by this amendment and support for the amendment may be found throughout the specification including at Table 1 on page 6 and paragraphs 24, 25, and 32.

Additionally, claims 3 and 24 are amended to clarify that the selected maturation stage has **both** a standardized concentration of chicoric acid and the highest observed level of immune-stimulatory or translation product. No new matter is added by this

amendment and support for the amendment may be found throughout the specification including at the abstract, paragraphs 5, 17, 24, 25, and 31-33.

Claim 23 is amended to clarify that it depends from pending claim 3 instead of cancelled claim 1. No new matter is added by this amendment and support for the amendment may be found at previously pending claims 1, 2, and 23 and paragraphs 27-28.

Claims 3 and 23 are objected to because they included a step of preparing an extract. Applicants have clarified that the claimed method does not include a step of preparing an extract. This objection is now moot Applicants respectfully request it be withdrawn.

Claims 3, 6, 7, and 23-25 stand rejected under 35 U.S.C. § 112, second paragraph as allegedly being indefinite. Specifically, the Examiner objected to the phrase "at least about 3.40%" as being indefinite. Applicants clarified this phrase to refer to a standardized concentration of "about 3.26 % to about 3.62%." The rejection is now moot Applicants respectfully request it be withdrawn.

The Examiner also objected to the phrase "optimal harvest window" as being indefinite. The Examiner kindly suggested clarifying this language by reciting a method for selecting a maturation stage of *Echinacea*. To expedite prosecution, Applicants clarified claims 3 and 24 so that they now refer to "selecting a maturation stage". The rejection is now moot Applicants respectfully request it be withdrawn.

The Examiner also alleged that the claim language referring to selecting a maturation stage with two characteristics was indefinite. According to the Examiner, the claim language would allow for two maturation stages to be selected. Applicants

respectfully disagree with this rejection. To expedite prosecution, however, Applicants clarified that the selected maturation stage *has both* (i) a standardized concentration of about 3.26% to about 3.62% chicoric acid and (ii) the highest observed level of immune-stimulatory product. The claims are not indefinite because the recited selection criteria are clear, definite and understandable to one of ordinary skill in the art. Indeed, the requirements of 35 U.S.C. §112 ¶ 2 are satisfied when the relevant criteria can be "calculated or measured." *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1558 (Fed. Cir. 1983). There is no objective evidence to demonstrate that one of ordinary skill in the art would not know how to select a maturation stage based on the above-stated criteria.

Applicants have chosen to define the invention in terms of two explicit selection criteria. A patentee is free to choose the means to point out and define its invention, and that "freedom of choice . . . should not be abridged." *See In re Chandler*, 319 F.2d 211, 225 (CCPA 1963). Because Applicants' chosen criteria do not render the claims "insolubly ambiguous" the claims cannot be invalid for indefiniteness. *See Bancorp Servs., L.L.C. v. Hartford Life Ins. Co.*, 359 F.3d 1367, 1372 (Fed. Cir. 2004). Applicants have overcome this ground of rejection and respectfully request it be withdrawn.

Claims 3, 6, 7, and 23-25 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. Specifically, the Examiner alleged that the reference in the claims to "a standardized concentration of at least about 3.40% of either chlorogenic acid or chicoric acid" adds new matter and/or is not adequately described. While Applicants disagree with this ground of rejection, to

expedite prosecution, Applicants clarified the rejected claim language by directing the claims to "a standardized concentration of about 3.26% to about 3.62% chicoric acid." As stated above, this amendment finds written description support in the application at least at Table 1 on page 6 and paragraphs 24, 25 and 32. Specifically, Table 1 shows the chicoric acid concentrations in *Echinacea* plants at various maturation stages. These concentrations range from 3.26 ± 0.10 (standard error) to 3.62 ± 0.11 (standard error) for maturation stages 1-6. Paragraphs 24 and 25 explain that the levels of chicoric acid in maturation stages 1-6 are suitable for standardized extracts. Indeed, paragraph 32 at page 9 explains that selecting maturation stage 1, 3, or 6 provides sufficient levels of a standardization marker (i.e. chicoric acid), while still providing the highest levels of immune stimulatory product. Thus, at least these portions of the specification provide written description support for claims 3, 6, 7, and 23-25 as clarified herein.

The Examiner also rejects the claim language that refers to a step of preparing a standardized extract as failing to satisfy the written description requirement. While Applicants respectfully disagree with this ground of rejection, to expedite prosecution Applicants deleted such language from the claims. The rejections for alleged lack of written description are now moot Applicants respectfully request that they be withdrawn.

Claims 3, 6, 7, and 23-25 are rejected under 35 U.S.C. § 112, first paragraph as allegedly failing to satisfy the enablement requirement because "while being enabling for a method for determining a maturation stage to harvest *Echinacea* plants," the specification allegedly fails to enable one to determine an optimal harvest window of *Echinacea* plants.

While Applicants respectfully disagree with this ground of rejection, to expedite prosecution, Applicants clarified that the claimed method is a method of selecting a maturation stage of an *Echinacea* plant, which is commensurate with the claim scope identified by the Examiner. In fact, at least Table 1 and paragraphs 24, 25, and 32 enable one of ordinary skill in the art to select a maturation stage having a chicoric acid concentration of about 3.26% to about 3.62%. The rejection is now moot and Applicants respectfully request that it be withdrawn.

Claims 3, 6, 7 and 24 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over Gahler (US 6,511,683) in view of the combination of newly cited Letchamo et al., "Factors Affecting Echinacea Quality," ASHS Press, Alexandria, VA (2002), Seidler-Lozykowska et al. (2003), Dou et al. (2001 – Abstract), and Rininger et al. (2000). Applicants respectfully disagree. Additionally, Applicants respectfully note that claims 23 and 25 are not rejected under 35 U.S.C. § 103 and respectfully request that these claims be allowed.

The present method is directed to a method for selecting a particular maturation stage of an *Echinacea* plant. The method requires, among other things, analyzing the cell culture for a level of immune-stimulatory product induced by the preparation; observing the level of the immune-stimulatory product corresponding to each of the different maturation stages; determining a concentration of a marker compound of each preparation at the plurality of maturation stages, wherein the marker compound is chicoric acid; and selecting a maturation stage that has both: (i) a standardized concentration of about 3.26% to about 3.62% chicoric acid as measured by high

performance liquid chromatography analysis; and (ii) the highest observed level of immune-stimulatory product.

In contrast, the disparate references cited by the Examiner all point to a process for harvesting the *Echinacea* plant at a selected stage where the amount of a certain marker, typically chlorogenic or chicoric acid, can be standardized at a desired level. Obviously, the art recognizes that certain regions of the world and certain harvest times will lead to plants containing a different amount of the marker. Such a recognition, however, does not teach or suggest to one of skill in the art that they should also analyze the same *Echinacea* plant for a level of an immune-stimulatory product **and** select the particular maturation stage that has the required concentration (i.e., about 3.26% to about 3.62%) of chicoric acid and the highest observed level of the immune-stimulatory product.

While it is true that it was known in the art to test *Echinacea* and *Echinacea* extract to determine if it exhibited immunostimulatory activity (Rininger), there is no teaching or suggestion that one of skill in the art would use such information **together with** a determination of a concentration of chicoric acid in an amount between about 3.26% to about 3.62% to select a maturation stage. At best, one of skill in the art upon reviewing Rininger would merely conclude that if one sought to use *Echinacea* for immunostimulatory activity, one of skill in the art should use the whole herb or root powder and not a standardized extract. This teaching is different from and not related to the present method which seeks to select a particular maturation stage based both the standardized concentration of chicoric acid (at a specified level, i.e., from about 3.26% to about 3.62%) and the highest observed level of immune-stimulatory product.

In short, even when each of the four references cited by the Examiner is combined, one of skill in the art is not led to the presently claimed method. Thus, despite the fact that the teachings of the cited references are like pieces of a puzzle, they do not fit together to arrive at Applicants complete method.

Applicants believe that currently pending claims 3, 6-7, and 23-25 are patentable. The Examiner is invited to contact the undersigned attorney for the Applicants at 312.321.4276 if such communication would expedite allowance of this application.

Respectfully submitted,

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